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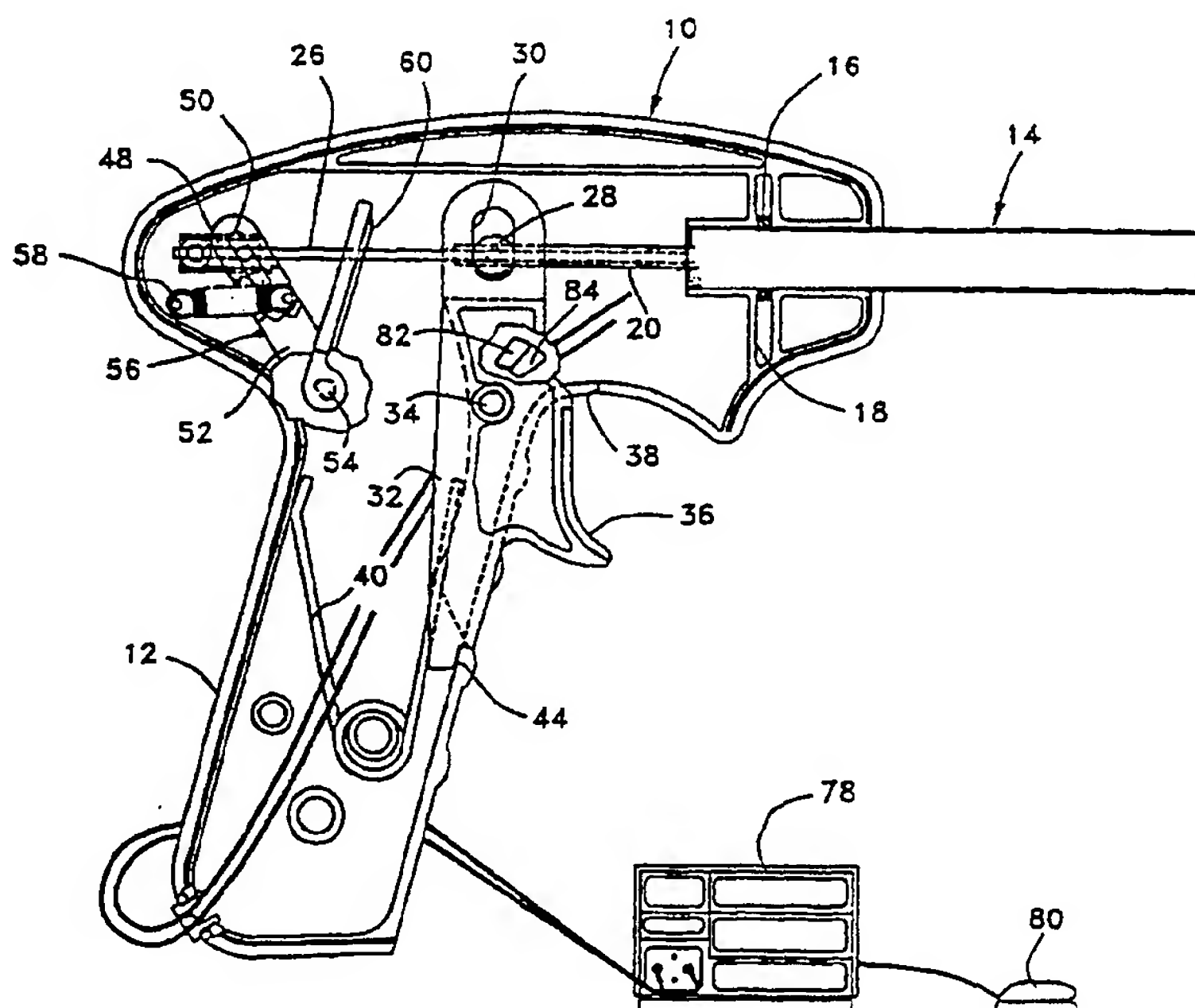
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(54) Title: CUTTING AND COAGULATING FORCEPS



## (57) Abstract

A cutting and coagulating forceps includes a housing (10) with a protruding barrel (14), and a pair of normally closed electrocautery jaws (22, 24) which are held closed by cam contact with the mouth (70) of the barrel (14) as the jaws (22, 24) are retracted by a spring (40). An independently sliding blade (62) which passes between the electrodes (22, 24) is provided. The jaws are opened by squeezing a trigger (36), and the blade (62) is advanced by pressing a lever (60) with the thumb. The jaws (22, 24) are designed to provide sufficient jaw strength within a barrel having an outside diameter of about five millimeters.

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Cutting and Coagulating Forceps

## BACKGROUND OF THE INVENTION

This invention relates generally to surgical instruments and, more particularly, to a grasping and cutting forceps.

Electrosurgery involves the application of electrical energy to tissues. Water is evaporated from tissues during electrosurgery, and with proper control of the intensity, frequency and duration of the applied energy, a surgeon can either coagulate or cut tissues.

A number of expired patents disclose electrocautery forceps having a pair of U-shaped jaws and a cutting wire which is advanced between the arms of the jaws to cut tissue clamped between them.

In the present invention, a purely mechanical shielded cutting blade is employed, in conjunction with bipolar coagulating jaws. Both the blade and the jaws are independently movable along the axis of the tool; each is retracted by a spring, so that the jaws are normally closed.

The invention described below is like that described in U.S. Patent 5,458,598, except that the jaws have been redesigned to fit within a shaft which is half the diameter, to permit use in procedures calling for a smaller tool, such as lysis of adhesions. Merely scaling down the prior design would have resulted in inadequate jaw strength.

## SUMMARY OF THE INVENTION

An object of the invention is to provide a small-diameter tool which can grasp and coagulate tissues, and then cut them while the grasp is maintained.

Another object of the invention is to enable a surgeon to move coagulating jaws and an associated cutting blade independently, without having to worry about interference between the blade and the jaws.

A further object is to enable a surgeon to rotate the

jaws about the axis of the tool.

These and other objects are attained by a reduced-diameter grasping, coagulating and cutting forceps including a handgrip-shaped housing with a protruding barrel, a pair of electrocautery jaws which are closed by interference with the mouth of the barrel when the jaws are retracted, and an independently movable blade disposed between the jaws. The jaws are opened by squeezing a trigger to advance them, and the blade is advanced by pressing a lever with the thumb.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings:

Figure 1 is a view of a grasping, cutting and coagulating forceps, partially sectioned on a vertical plane substantially bisecting the device, showing the handle of the forceps and a rear portion of a barrel;

Figure 2 is an oblique view of the tool shown in Fig. 1, with a smaller diameter barrel;

Figure 3 is a sectional view, taken from the side, of the front portion of the barrel and jaws protruding therefrom, with the cutting blade in its advanced position;

Figure 4 is a top sectional view thereof, but with the blade retracted;

Figure 5 is a perspective view of the distal end of the forceps;

Figure 6 is a sectional view taken on the line 6-6 in Figure 4;

Figure 7 is a perspective view of a modified molded plastic jaw assembly, with a blade between the jaws;

Figures 8 and 9 are isometric views of the distal end of the forceps, showing the modified jaws opened and closed, respectively;

Figure 10 is a detail of a metal electrode;

Figure 11 shows the electrode molded into a jaw subassembly;

Figures 12 and 13 show two such subassemblies being

prepared for a final molding step to connect them together;

Figure 14 shows the final jaw assembly;

Figure 15 shows a modified form of the jaw assembly;

Figure 16 is an isometric view of the forceps, modified  
5 by the addition of a jaw rotating wheel;

Figure 17 is a sectional view of the forceps, looking in  
the distal direction, showing a thumb wheel and rotary  
electrical joint;

Figure 18 is a side view of the elements shown in Figure  
10 17;

Figure 19 is a top view thereof;

Figure 20 is a sectional view, like Figure 17, of a  
second embodiment of the invention;

Figure 21 is a side view of the elements shown in Figure  
15 18; and

Figure 22 is a top view thereof.

As used herein, the term "proximal" means toward the end  
of the forceps closer to the handle; "distal" connotes the end  
from which the jaws extend.

## 20 DESCRIPTION OF THE PREFERRED EMBODIMENT

A grasping and cutting forceps embodying the invention  
includes a molded plastic housing 10 (Fig. 1) having a down-  
wardly extending handle 12. A presently preferred material  
for the housing is produced by Monsanto under the trademark  
25 Lustran ABS. The housing is formed in substantially symmet-  
rical halves joined on a vertical plane of symmetry "V".  
A tubular barrel 14 protrudes from the forward end of the  
housing, where it is retained between the halves by the  
combination of a fitting 16 secured to the rear of the barrel  
30 and a corresponding annular groove 18 in the housing.

The barrel shown in Figure 2 has an outside diameter of  
about five millimeters or less. The items running coaxially  
through the barrel 14 are flattened, stiff stainless steel  
wires which are flattened to form elongate tines 21 capable of

substantial bending. They are connected at their forward or distal ends (Fig. 4) to respective jaws 22,24, and can move along the axis of the barrel to advance and retract the jaws. A slender push rod 26, movable independently of the tines, runs along the axis of the barrel, between the tines, to move a cutting blade 62.

The rearward (proximal) ends of the tines 21 (Fig. 2) are clamped within a compression fitting 27 which in turn is connected by means of a metal tube 20 to a clevis 28 confined within vertically extending slots 30 at the upper end of spaced arms of an actuating lever 32. The lever is supported within the housing by a pin 34 (Fig. 1), whose ends are supported by the housing. The lever is concealed, except for a trigger portion 36 that extends through a slot 38 at the forward side of the handle. When the trigger is squeezed toward the handle 12, it pivots the lever 32 in one direction (clockwise, when viewed from the right side of the tool as in Figure 1) and the tube 20 pushes the tines 21 and the compression fitting 27 (Fig. 2) forward. A hairpin-type torsion spring 40 (Fig. 1) engaging the bottom of the lever biases the lever counterclockwise to a rest position defined by a stop 44 at the bottom of the lever. Clockwise movement of the lever is limited by interference between a pin 82 on the lever and the slot 84 through which it protrudes.

The rear end of the push rod 26 is secured to a ball clevis 48, having set screws for adjustment, that rides in a slot 50 at the upper end of an idler arm 52 within the housing, supported on a transverse pivot shaft 54. The idler arm is normally drawn rearward, against a stop pin 56 in the housing, by a tension spring 58. The pivot shaft extends from both sides of the housing. Symmetrical thumb levers 60 are installed on the pivot shaft's ends, outside the housing. The pivot shaft's ends are provided with flats, keys or non-circular cross-sections to lock them to the thumb levers. Pressing either thumb lever forward pivots the shaft and the idler arm, driving the push rod 26 forward. Providing two thumb levers makes the device ambidextrous, but one could



modify the device by omitting one of the levers, if desired.

The coagulating jaws 22, 24 extend beyond the barrel mouth 70 a variable distance, depending on the trigger pressure and the thickness and nature of any tissues captured between the jaws. Maximum jaw stroke is about 0.25 inch (6.25 mm). Each jaw is cut from stainless steel stock by electric discharge machining, so that it has a "U" shape when viewed vertically, as in Figure 4, and is rather flat when viewed from the side.

The jaws have uncoated, serrated mating surfaces 64, each comprising about thirteen teeth (extending across both arms of the "U") having a pitch of about .029 inch (7.4 mm). The crests are rounded at a radius in the range of .001-.007 inch (0.25 - 1.77 mm). The oblique faces of the teeth lie at an angle of about 57° to the length of the jaws, and the teeth are arranged so that they mesh when the jaws close about a horizontal plane "H". One can see that the jaws converge at a slight angle toward the tip. The reason for the convergence is that, otherwise, the jaws would contact each other first at their proximal ends, closing the circuit and preventing current from reaching the tips.

The arms of the jaws are shaped so as to form what appears, when viewed from the side in Figure 3 as a bulge comprising proximal diverging segments 66 and distal converging segments 68. The bulge is larger than the barrel diameter, so that the diverging segments act as camming surfaces against the internally beveled mouth 70 of the barrel when the jaws are retracted.

The arms of the jaws also have two outwardly deflected or "kicked-out" portions, when viewed from the top, forming a widened gap in the vicinity of rear of the blade. The widened gap avoids binding between the arms and the distal end of the blade push rod,, which would otherwise occur when the jaws were retracted and forced closer together by the barrel.

The jaws and their supporting tines are entirely covered (except for the jaws' tips, their serrated mating surfaces, and the tines' proximal ends) with a dielectric thermosetting

polymeric resin material 72 which prevents electrical contact between the tines and the barrel. The material is sprayed on as a liquid, while the tips and serrated surfaces are protected from the spray by masking. Heat is then applied to set the resin. A preferred polymer for the coating is polyurethane having a tensile strength of about 10,000 psi and a dielectric strength of about 5600 volts per mil, applied to achieve a final thickness of 3 - 10 mils.

The tines are kept separate, within the barrel, by at least one plastic spacer 90 (Fig. 6) having a cylindrical envelope. The outside diameter of the spacer is slightly less than the inside diameter of the barrel, to permit the spacer to slide fore and aft as the device is operated, while preventing unacceptable levels of inflation gas leakage past the spacer. Two diametrically opposed recesses 92 are formed in the spacer, each extending parallel to the length of the barrel, and each having a cross-section like that of the tines. The tips 94 at either end of each recess are spaced closer than the tine width, so that during assembly, the tines snap into the recesses. The presently preferred material for the spacer is an ABS sold under the trademark Lustran 248; however, other materials may prove suitable.

Flexible conductors 76 are electrically connected to the proximal ends of the jaw wires, by means of the compression fitting 27 mentioned above. The fitting consists of two coaxial components, the inner one of which spaces the tines apart and is insert molded onto a grooved tube which supports the push rod 26. The external component surrounds the internal component and has holes receiving set screws which press the conductors against the respective tines. These conductors, shown diagrammatically, pass down through the handle and out the bottom to suitable connectors (not shown) which may be plugged into a power supply 78 controlled by a foot switch 80.

A cutting blade 62 (Figs. 3 - 5) is affixed to the distal end of the push rod 26. The blade is oriented perpendicular to the jaws, so that it is positioned in the gaps between the



arms of each "U", with the cutting edge of the blade extending vertically. The blade is substantially rectangular, having a sharp, square cutting edge at its forward end, and a width providing a close sliding fit within the barrel. The rear  
5 edge of the blade is rigidly affixed to the forward end of the blade push rod by welding or brazing, for example. The rod's diameter is substantially greater than the blade thickness.

As can be seen in Figure 3, the cutting edge is about even with the front end of the barrel when the blade is in its  
10 normal rest position (retracted). In this position, the blade is shielded by both the barrel and the jaw tips 65 to help prevent accidental cuts. The blade's maximum stroke is about 0.60 inch (15 mm) when the jaws are fully extended, but less when the jaws are retracted.

As mentioned, both the jaws and the blade can be indepen-  
15 dently reciprocated by the surgeon. But, were the blade to be extended so far as to contact the looped end of the jaws, not only would be the blade edge be dulled, but also the blade would short the electrical path between the jaws. Thus, it is  
20 important to prevent overextension of the blade, and yet to maximize the stroke of the blade when the jaws are not retracted fully.

To prevent overextension, forward blade motion is controlled by a stop whose position is a function of jaw  
25 extension. This result is obtained by providing a movable stop for the thumb lever. The stop is in the form of a pin 82 protruding from the actuating lever 32, through a slot 84 in the housing 10. The flattened rear surface on the pin is engaged by the forward side of the thumb lever just before  
30 the blade contacts the jaw tips, regardless of jaw position. Inasmuch as the pin is above the trigger pivot, it moves in the same direction as (but less rapidly than) the jaws. The further forward the jaws are advanced by squeezing the trigger, the further forward the stop is, allowing the blade  
35 to be advanced farther. Conversely, the range of blade movement is reduced substantially when the trigger is released, to protect the blade and prevent unwanted electrical contact.

In use, tissue is grasped between the jaws by first squeezing the trigger to open the jaws, then advancing the jaws over the tissue and releasing the trigger. The torsion spring pulls the jaws back into the mouth of the barrel, whose camming action drives the jaws together, clamping the tissue. We prefer that the retracting spring force and jaw geometry are chosen to produce a clamping force in the range of 1 - 3 pounds, which is sufficient, with the jaws described, to produce a maximum pulling force of at least one pound on the tissues. Now, when the surgeon depresses the foot pedal 80, a high frequency voltage is impressed across the jaws, to coagulate the tissues. Once the tissues have been sufficiently coagulated, the foot pedal is released, and -- while the tissues are still held by the jaws -- the blade is advanced, cutting through the tissues, by pressing one of the thumb levers forward. When pressure on the thumb lever is removed, the tension spring retracts the blade. Finally, the tissue is released by squeezing the trigger.

The surgeon also can perform spot coagulation by touching the uncoated tips of the jaws to tissues.

#### Modified jaw construction

Figure 7 shows a modification in which the jaws are formed of a molded plastic, rather than metal. The plastic jaws 122, 124 have serrated mating inner surfaces 164, each comprising about ten teeth having a pitch of about .076 inch (1.8 mm). The oblique faces of the teeth are at about 45° to the length of the jaws, and the teeth are arranged so that they mesh when the jaws close about a horizontal plane "H". One can see that the jaws converge at a slight angle toward the tip. The reason for the convergence is that, otherwise, the jaws would contact each other first at their proximal ends, closing the circuit and preventing current from reaching the tips.

On their outer surfaces, proximal to the teeth, the jaws have enlargements 166. Even when the jaws are closed, the distance spanned by the enlargements is greater than the

barrel diameter, so that the proximal, diverging ramp surfaces 168 of the enlargements act as camming surfaces against the internally beveled mouth 170 of the barrel. A camming action drives the jaws together when they are retracted (Fig. 9).

5 Metal electrodes 172, 174, each preformed from stainless wires having a rectangular cross-section into substantially a "U" shape, are molded into the jaws 122, 124. Each electrode has a distal portion which passes around the teeth at the jaw tips 165, with its sides exposed to permit the surgeon to  
10 coagulate small bleeders without having to grasp them. The proximal ends of the electrodes are embedded within the plastic; intermediate portions of the electrodes, offset inward from the distal portions, extend through slots formed in the first few jaw teeth.

15 The proximal ends of the electrodes are molded within the cylindrical plastic plug 121, which electrically insulates the wires from one another, as well as from the barrel. The plug has a close sliding fit within the barrel, so that it functions as a dynamic seal to prevent loss of inflation gas from  
20 the surgical site. The presently preferred material for the plug and jaw assembly is Hoechst Celanese's Vectra LCP (a liquid crystal co-polyester amide); however, other materials may prove suitable, including General Electric's Ultem (polyetherimide resin), General Electric's Lexan (a polycarbonate),  
25 and Monsanto's Lustran SAN (a styrene-acrylonitrile).

One proximal end of each electrode protrudes from the proximal end of the plug; the two ends are spaced and shaped to fit within a standard female connector installed at the end of the conductors which pass through the housing.

30 The jaw assembly is described as "integral" in that it cannot be disassembled, and its parts are integrated by molding. However, the assembly may be produced in several steps, illustrated in Figures 10 - 14. Figure 10 shows one metal electrode 172, ready for insertion molding into a sub-  
35 assembly (Fig. 11) comprising one jaw, the embedded electrode, and half of the plug. One end of the electrode protrudes from the proximal end of the plug half. Figure 12 shows two sub-

assemblies 190 being placed together over the end of the tube 20. Note the flats 192 at the end of the tube, which engage within corresponding 194 flats molded in the subassemblies. Figure 13 shows a ring 196 being installed to hold the plug halves together, and a cap 198 for holding the jaw tips together, as material is molded around the plug halves to form the finished assembly shown in Figure 14.

Figure 15 illustrates a modified form of the invention, where the blade is wholly enclosed by the jaws, to better shield the blade and thus prevent accidents. We prefer to use a clear plastic such as Lexan for this application.

#### Rotatable jaw description

In another modified form of the invention, the jaws can be rotated or turned within the barrel. As one can see from Figs. 16 - 22, the jaw actuating tube 20 passes through an electrical joint including a rotor 286 in which the tube 20 is secured by adhesives, molding, or an interference fit. The rotor has opposed flats 288, visible in Figure 16, which engage corresponding flats on the interior surface of the thumb wheel 290, and prevent relative rotation. This spline connection might take other forms. In any event, there is a sliding fit between the rotor 286 and the thumb wheel 290, so that the rotor can move fore and aft as the jaws are actuated and released, without requiring like movement of the thumb wheel. The thumb wheel is prevented from moving substantially in the axial direction, because it protrudes laterally through two slots 292 in the forceps body, one on either side. The slots are just wide enough to permit free movement of the thumb wheel.

The conductors 276, extending rearward from the plug at the middle of the barrel, terminate at the thumb wheel 290, where they are connected by soldering, for example, to electrodes 294 which are embedded in the thumb wheel and pass from its distal face to respective annular electrodes 296, 298 which function as slip rings. Each electrode is borne against by a brass contact or brush 300 having a spring bias forcing



it against a respective one of the rings. Each brush is heat-staked to the inside surface of the body at 302. The brushes are in turn electrically connected to the electric wires 304 which pass out through the bottom of the handle to a power supply, as mentioned previously. The thumb wheel, slip rings and brushes function together as a rotary joint to permit unlimited jaw rotation.

In one embodiment of the invention (Figs. 17 - 19), the slip rings 296, 298 are concentric members of different diameter, formed with coplanar annular contact surfaces, facing rearward. That is, the exposed contact surface of each ring is in a plane perpendicular to the axis of the tool.

In a second embodiment of the invention (Figs. 20 - 22), the slip rings 396, 398 are not coplanar, being offset in the axial direction, and their contact surfaces are cylindrical; that is, the outer circumference of each ring is its contact surface, and the brushes bear inward against the respective rings. Manufacturing considerations have led us to make these rings different diameters, but it is conceivable that they might be identical.

In either embodiment, the periphery of the thumb wheel 290 is irregular, having the general shape of a star whose eight rounded points 306 provide added traction and feel. The preferred drag provided by the thumb wheel and electrical contacts is about 0.3 inch-pound (3.3 gram-meter). When the jaws are retracted, in wedging contact with the barrel mouth, the torque required to turn the jaws will of course be higher. One may add detents (not shown) at equal intervals, for example every 45°, to give the surgeon an indication of how much he has turned the wheel. The detents may be ridges or depressions formed right in the slip rings, if desired.



CLAIMS

1. A normally closed coagulating and cutting forceps comprising

a housing,

5 a tubular barrel extending from a forward end of the housing, the barrel having an open mouth at its distal end, a pair of jaws, each partially protruding from the mouth of the barrel, said jaws being movable in a direction parallel to the axis of the barrel,

10 said jaws having opposed mating surfaces, and being constructed so that the jaws tend to spring away from each other, but are normally driven closed by contact with the barrel mouth as the jaws are partially retracted into the barrel,

15 a spring for retracting the jaws into the barrel, so that the jaws are normally closed and can clamp tissues while retracted,

means for advancing the jaws to release said tissues,

20 a cutting blade disposed between the jaws, and being movable along the axis of the barrel independently of the jaws, and

means for advancing the blade along the barrel axis to cut said tissues.

2. The invention of claim 1, characterized in that said jaws  
25 comprise a pair of elongate metal tines extending through the barrel, and

a spacer, slidable within the barrel, for maintaining spacing between said tines.

3. The invention of claim 2, further comprising lead wires  
30 extending through said body,

means for connecting each of said lead wires to a respective one of said tines,

and means for connecting said leads to a power supply for generating an alternating coagulating electrical current,

whereby said current is conducted to said jaws, for coagulating tissue clamped between the jaws.

4. The invention of claim 2, characterized in that the dielectric spacer has opposed recesses for laterally receiving the resilient tines, said recesses being designed to provide a snap fit for the tines in the recesses.

5. The invention of claim 4, characterized in that the dielectric coating on the jaws is formed by spraying their outer surfaces with a thermosetting resin, and then heating the material sufficiently to set the resin.

6. The invention of claim 2, characterized in that the jaw moving means comprises

a lever pivotally mounted within the housing and having a trigger protruding from the housing whereby the lever can be pivoted in one direction by squeezing the trigger,

a return spring for pivoting the lever in the opposite direction, and

means connecting an upper end of the lever with said resilient tines.

7. The invention of claim 6, characterized in that said connecting means comprises a compression fitting linked to the upper end of the lever, said compression fitting securing the proximal ends of said resilient tines.

8. The invention of claim 7, characterized in that the blade moving means comprises at least one thumb lever pivotally supported on the housing, a push rod affixed to said blade, and means linking the thumb lever to the push rod.

9. The invention of claim 8, characterized in that the push rod passes through said spacer and between said resilient tines.

10. The invention of claim 8, characterized in that the linking means comprises a pivot shaft supporting said thumb lever, an arm within the housing connected to the pivot shaft, and a clevis connecting one end of the push rod to the arm.

5 11. The invention of claim 1, characterized in that said blade has a width providing a close sliding fit with the inside diameter of said barrel

10 12. The invention of claim 11, characterized in that each jaw has an outwardly deflected portion forming a widened gap in the vicinity of the rear of the blade to avoid binding against a distal end of the blade push rod when the jaws are retracted.

15 13. The invention of claim 1, characterized in that said jaws are molded in one piece from a polymeric plastic, and are integral with a polymeric plastic plug having a sliding fit within the barrel, said jaws partially protruding from the mouth of the barrel, and each having an enlargement on its outer surfaces for engaging the barrel mouth and forcing the jaws closed as the jaw assembly is retracted, and a spring for  
20 retracting the jaw assembly into the barrel.

25 14. The invention of claim 13, characterized in that said jaws have flexible arm portions which extend from the distal end of the plug, said arms being molded with the plug and diverging slightly so that the jaws tend to open in the absence of closing force from the cam means.

30 15. The invention of claim 14, further comprising a pair of metal electrodes, one molded into each of said jaws and having a distal portion which passes around the tip of its respective jaw and opposes the corresponding portion of the other electrode.

16. The invention of claim 1, further comprising means for rotating said jaws within said barrel, independently of both axial jaw movement and axial blade movement.

17. The invention of claim 16, characterized in that the jaws  
5 are electrically isolated from one another and from the cutting blade and the barrel, and further comprising

conductor means for connecting two leads from a power supply to respective ones of said jaws, said conductor means including a rotary electrical joint capable of unlimited  
10 rotation, for transferring current from said leads to said jaws.

18. The invention of claim 17, characterized in that the rotary electrical joint comprises a rotor supporting a pair of slip rings, each of said slip rings being electrically  
15 connected to a respective one of said jaws, and a pair of brushes, fixed within the housing, said brushes being electrically connected to said leads, and bearing against said slip rings so as to maintain a conductive path between the leads and the slip rings.

19. The invention of claim 18, characterized in that the slip  
20 rings have planar contact surfaces lying in a common plane perpendicular to the barrel axis.

20. The invention of claim 18, characterized in that the slip  
25 rings have cylindrical contact which are axially offset along the barrel axis.

21. The invention of claim 18, further comprising a thumb wheel for turning the rotor and thus the jaws, the thumb wheel and rotor being interconnected by a spline connection permitting relative axial movement, but not relative rotation,  
30 between the thumb wheel and the rotor.

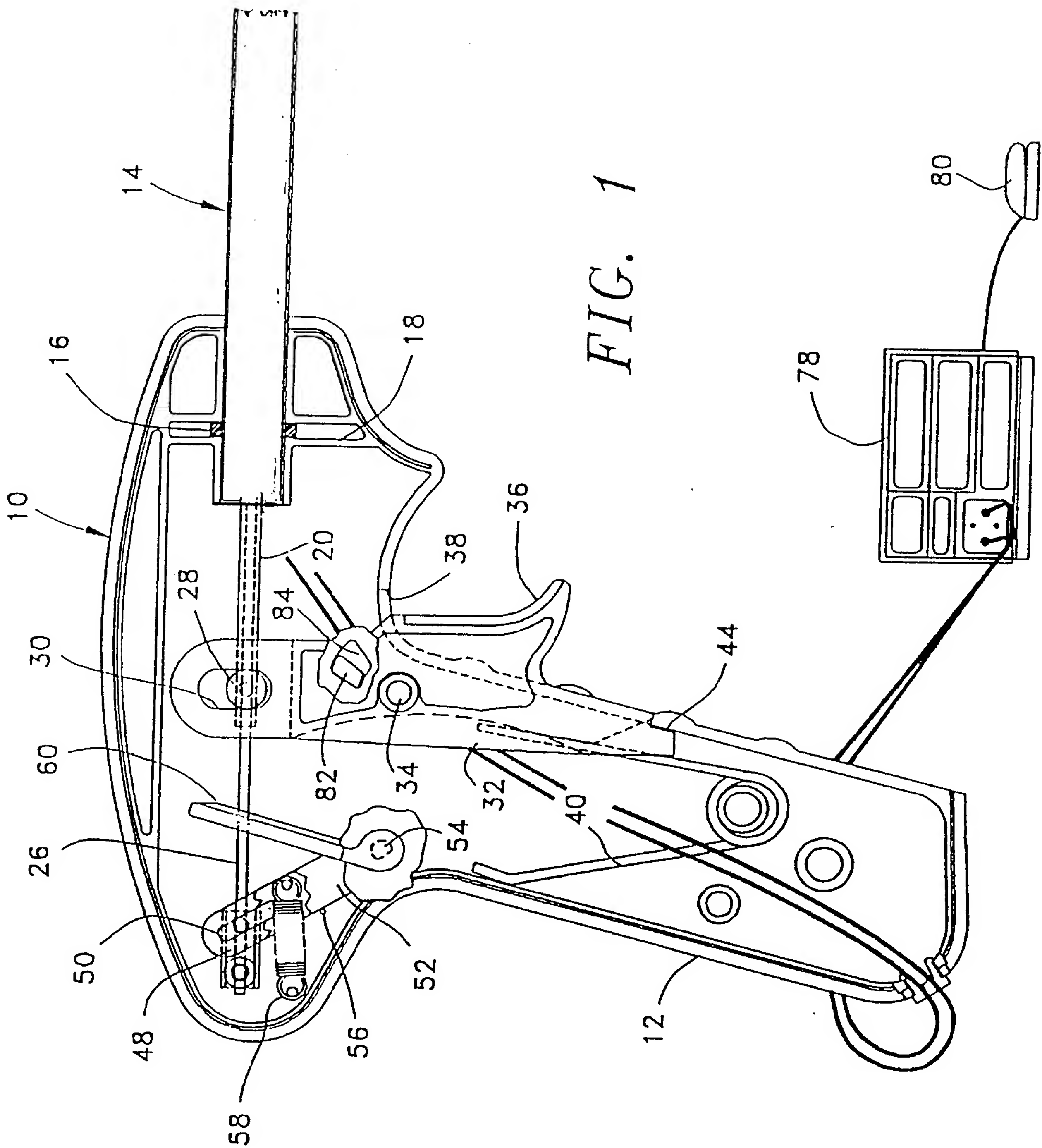
22. The invention of claim 21, characterized in that the body has two lateral slots through which portions of the thumb wheel protrude so as to be accessible.

23. The invention of claim 22, characterized in that the  
5 thumb wheel has an irregular periphery for improved traction.

24. The invention of claim 22, characterized in that the thumb wheel has detents to provide a tactile feedback as the jaws are rotated.

25. The invention of claim 22, characterized in that the  
10 rotor has detents to provide a tactile feedback as the jaws are rotated.





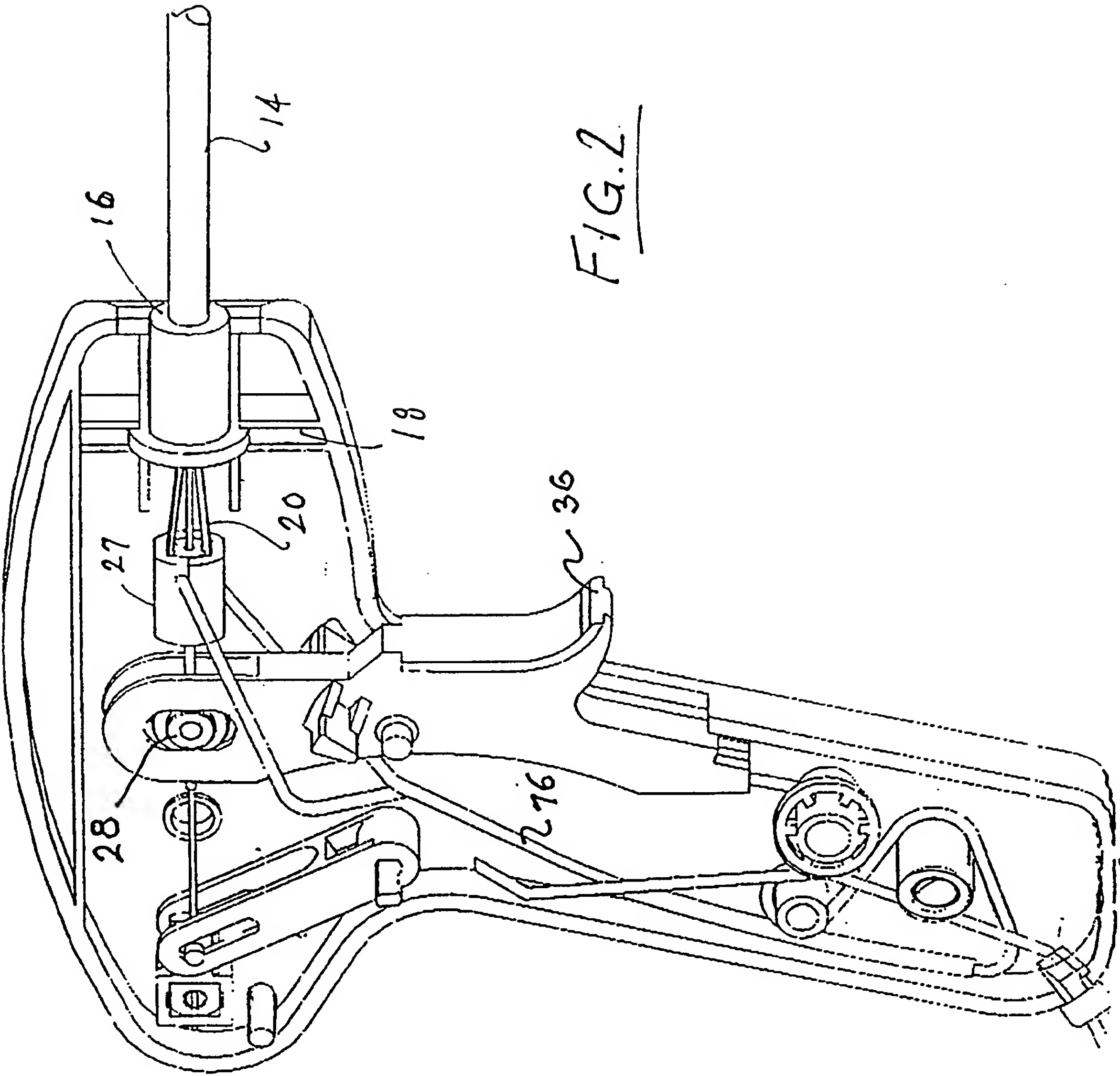


Fig. 4

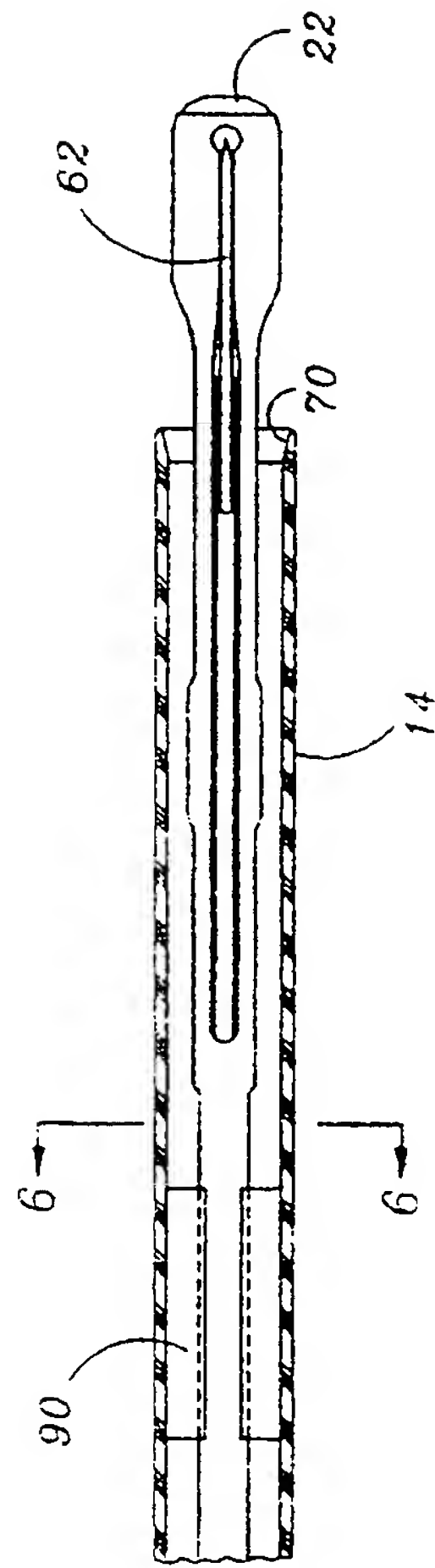
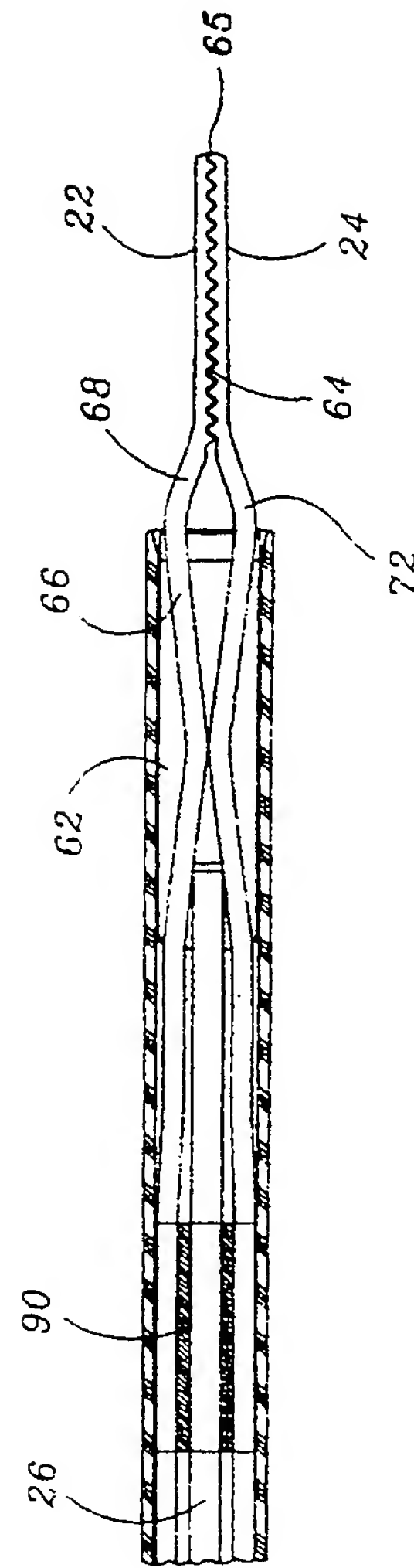


Fig. 3



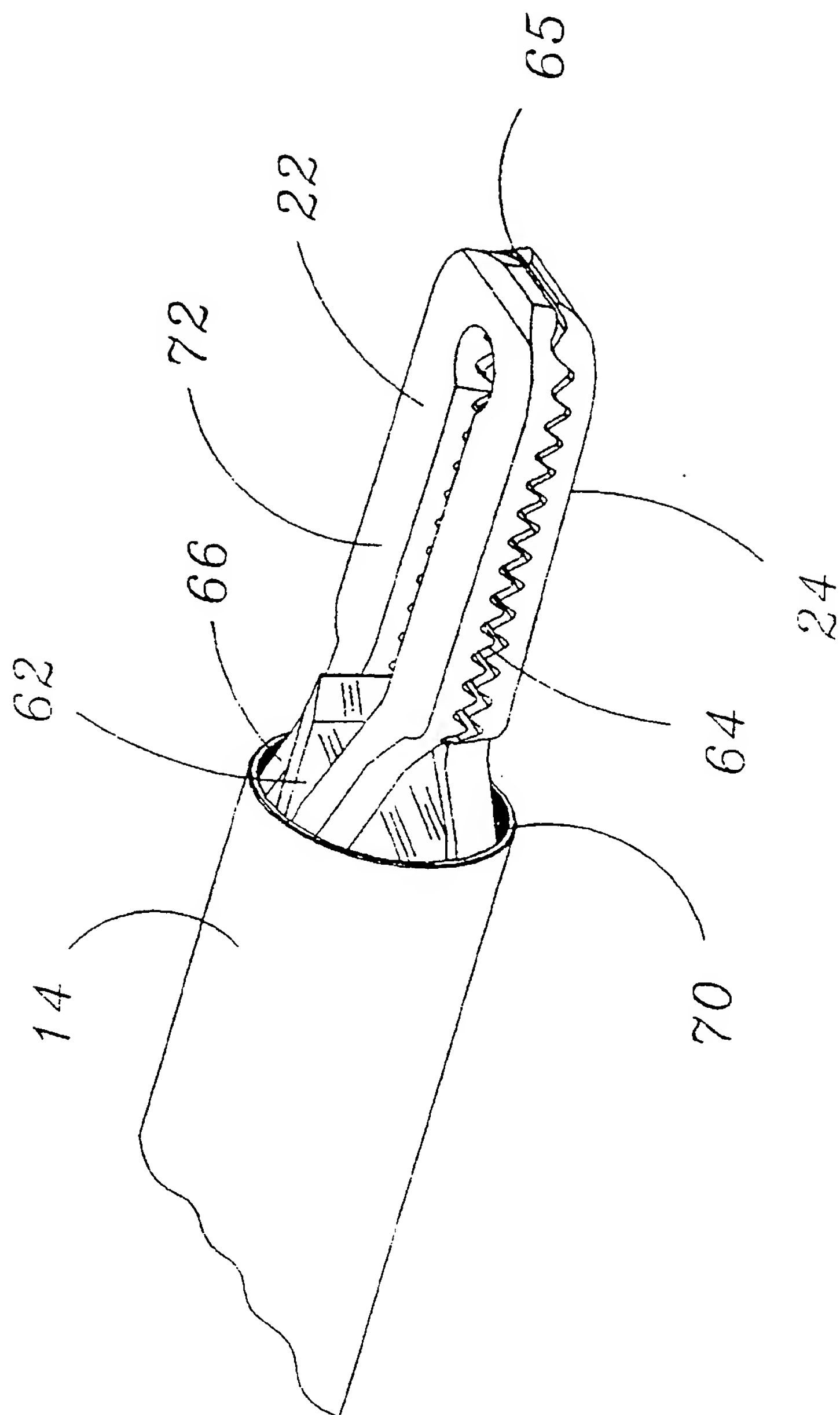


FIG. 5

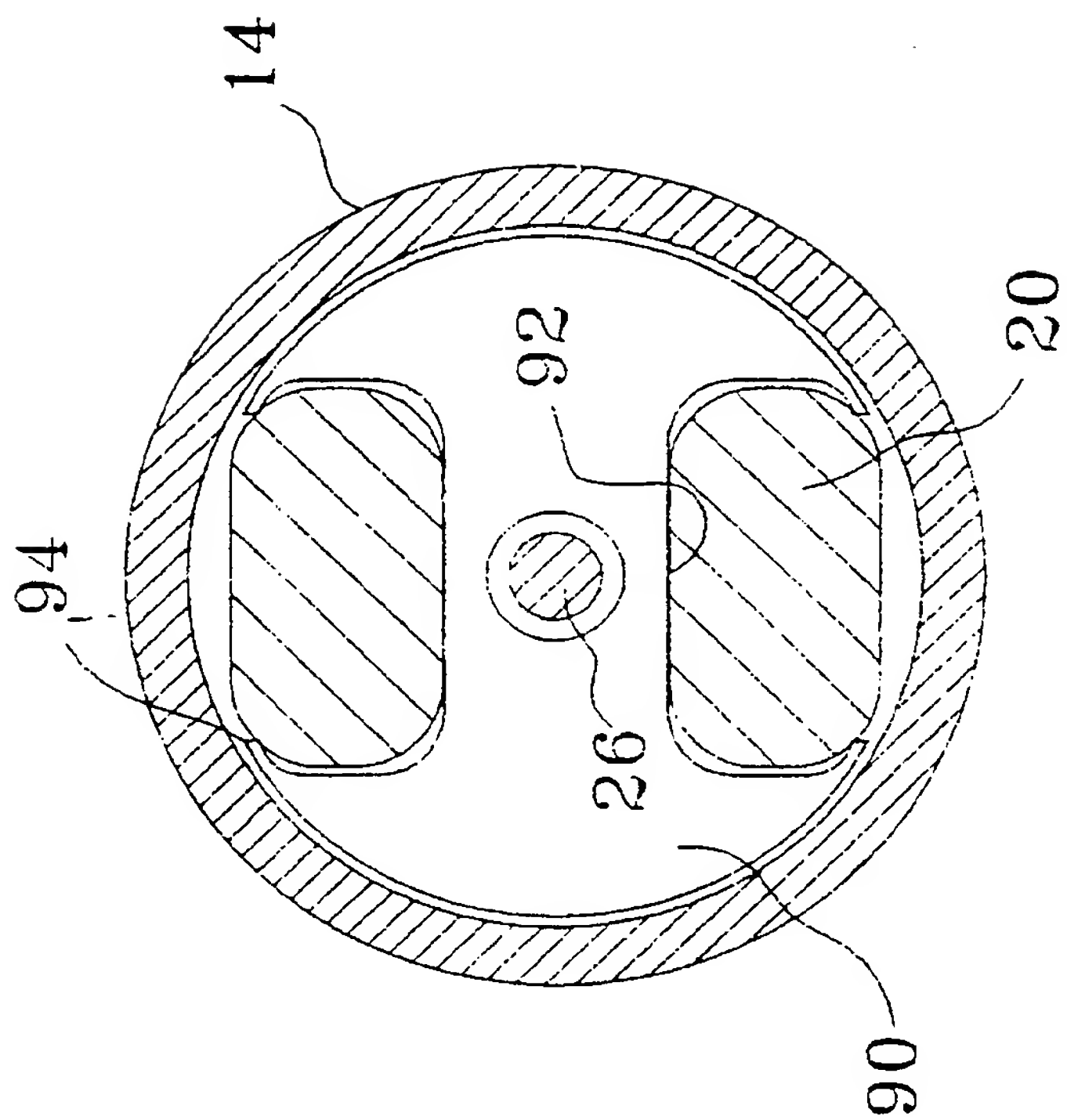


FIG. 6



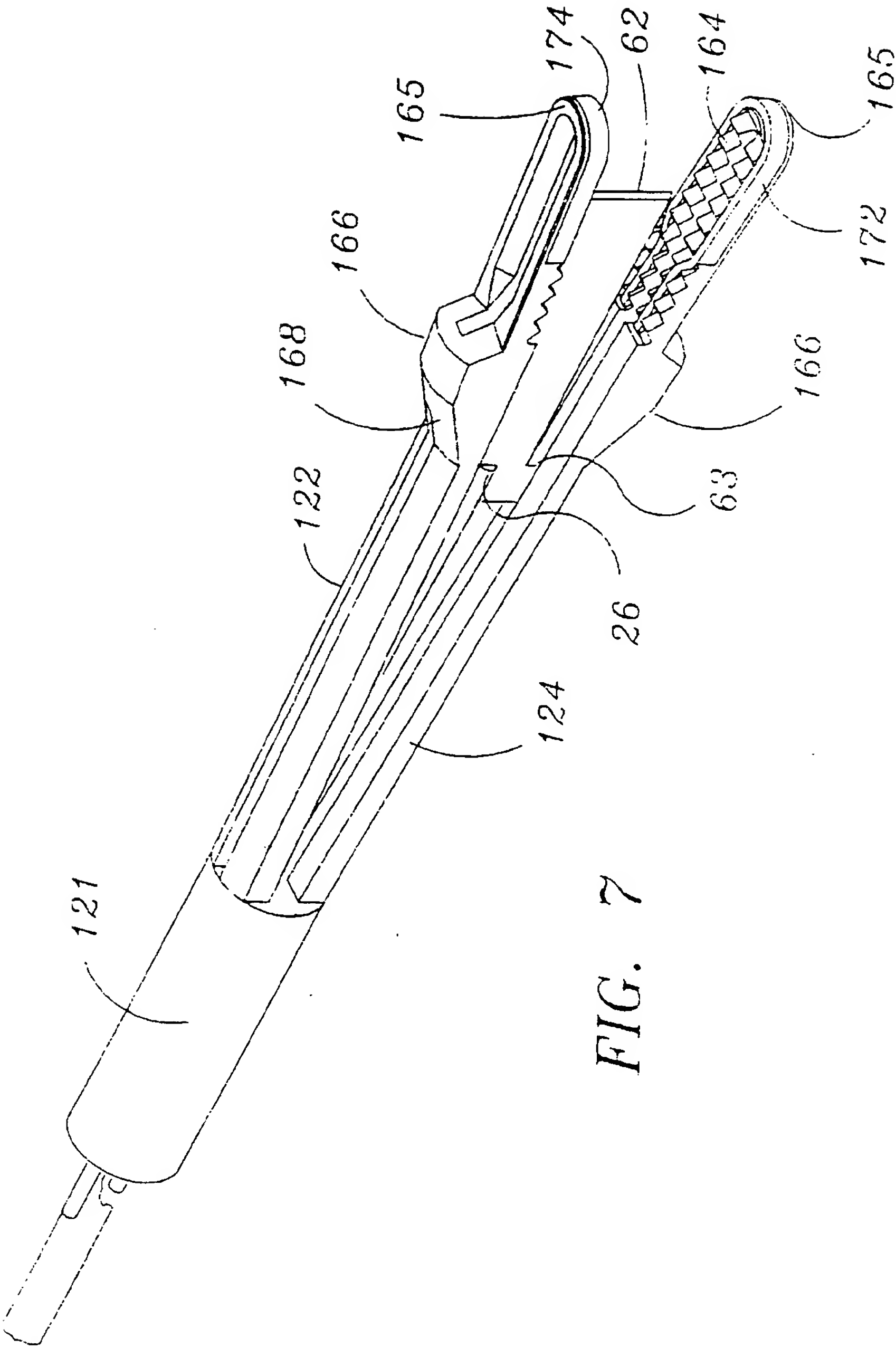
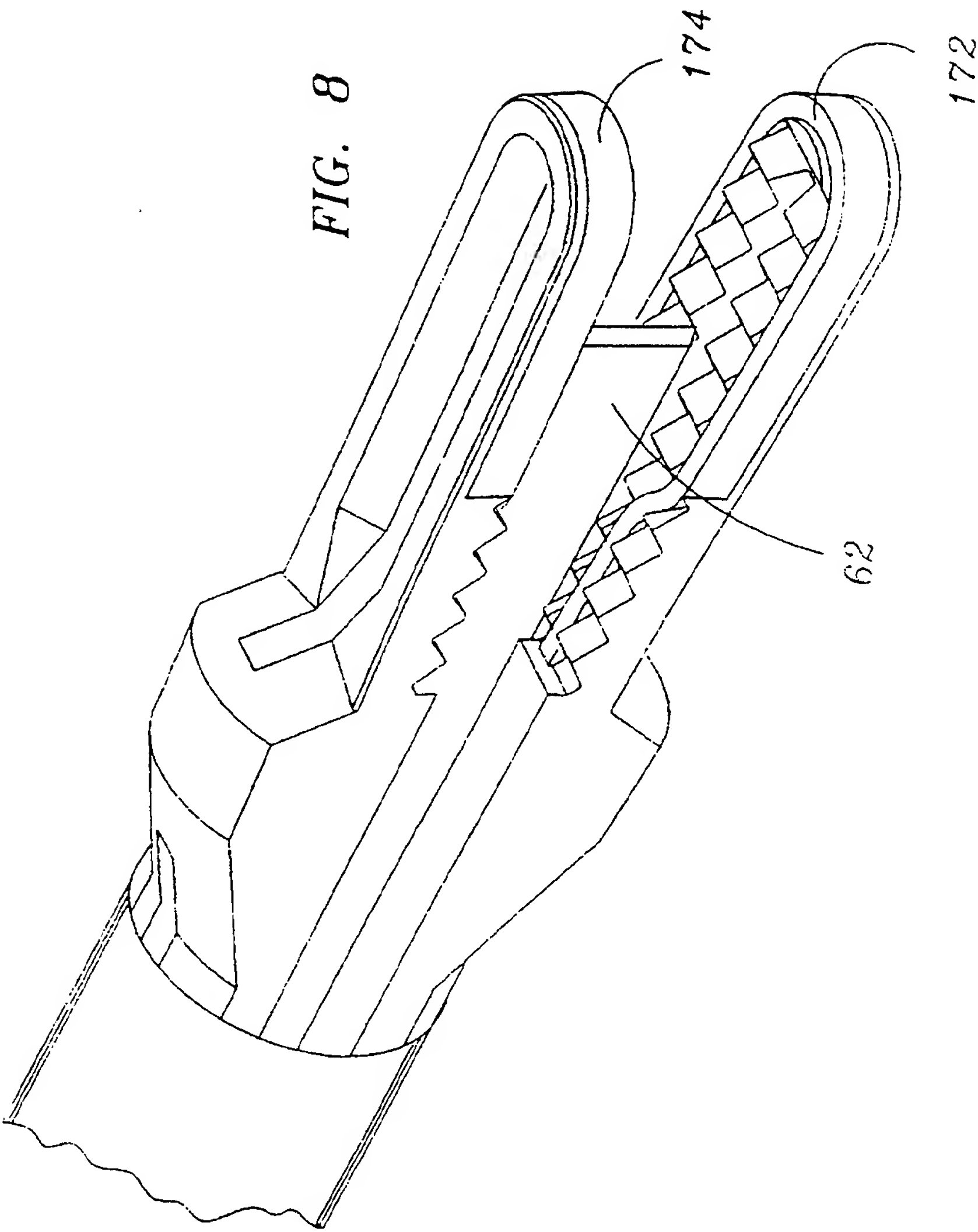
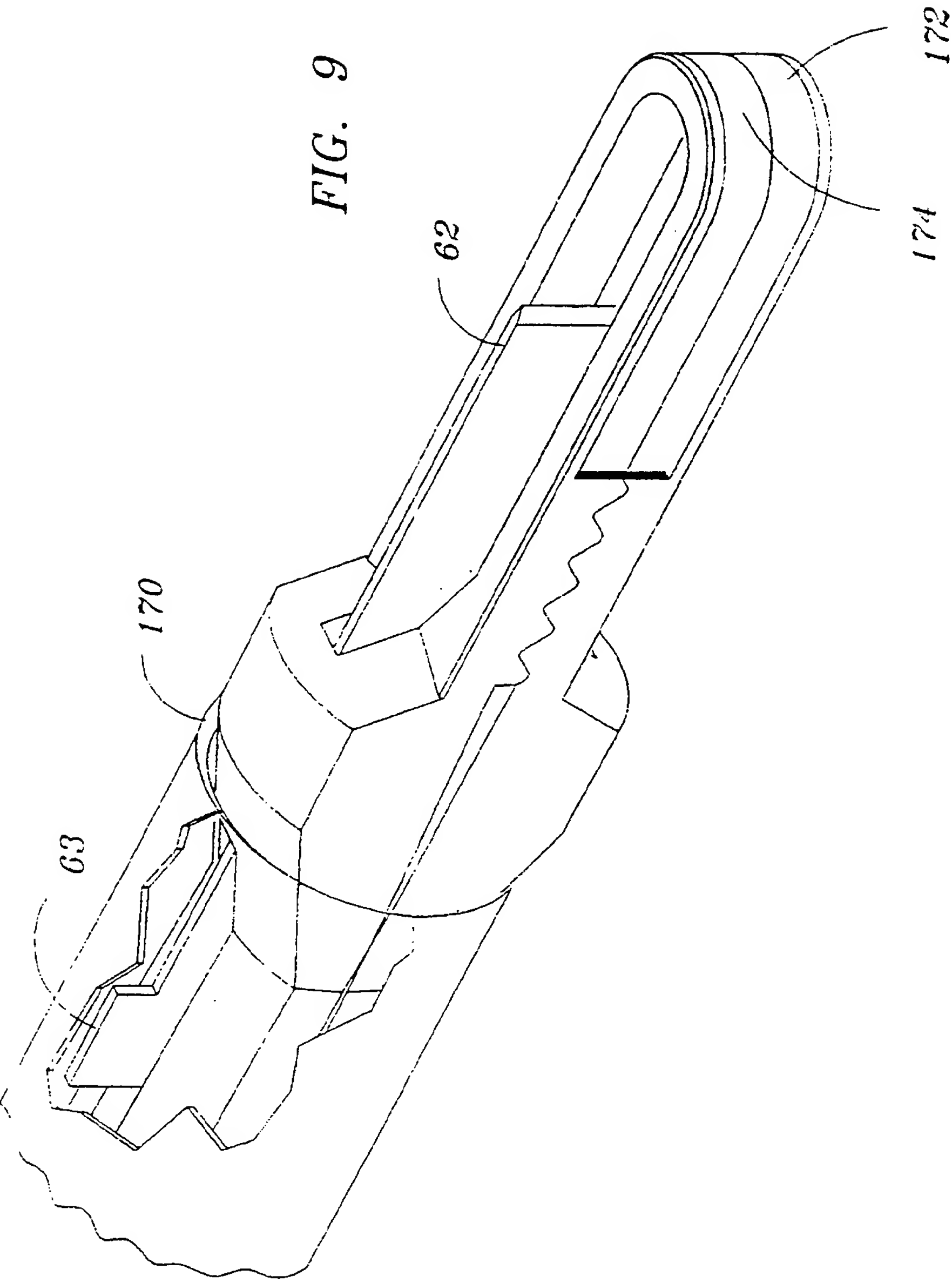


FIG. 7





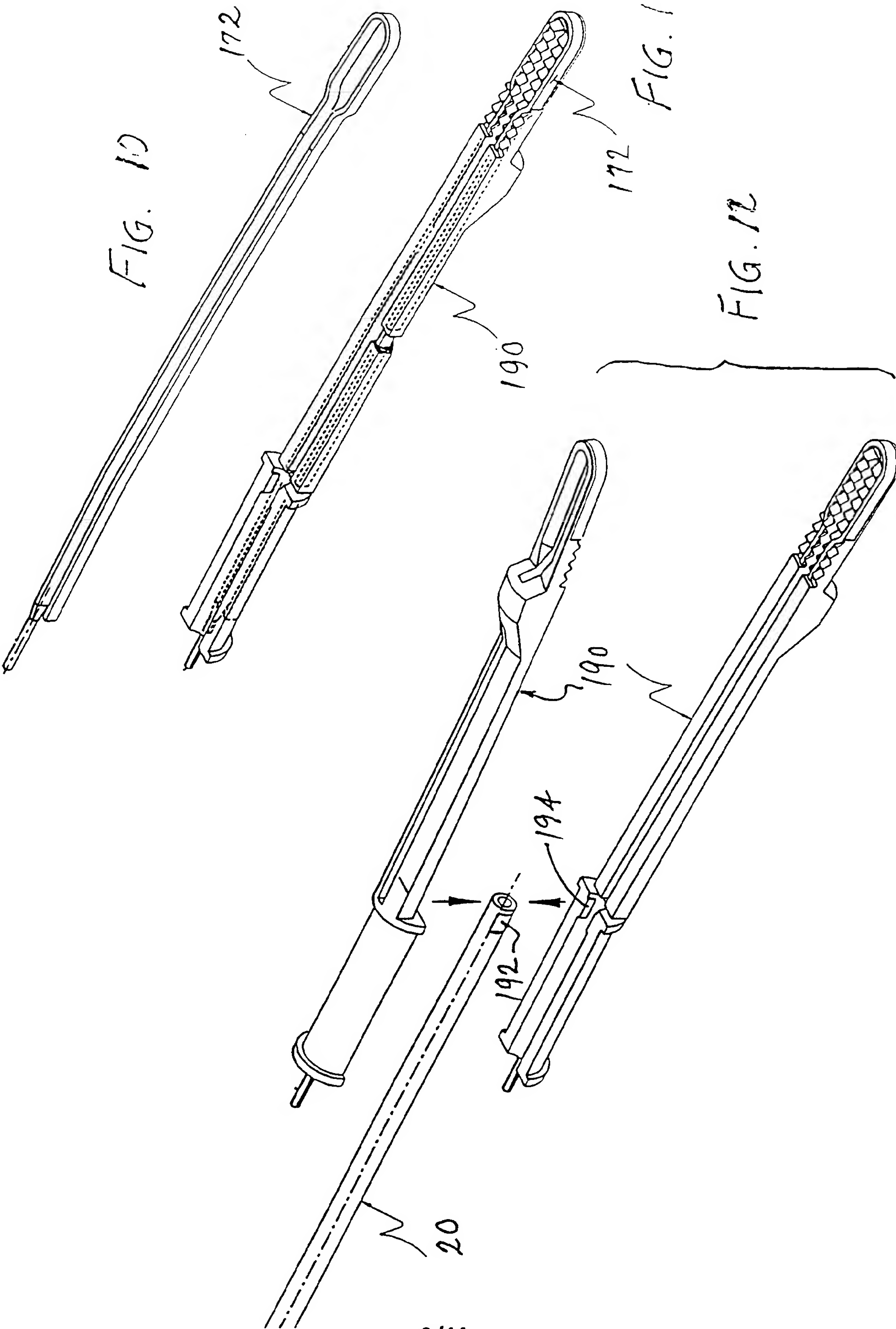


FIG. 13

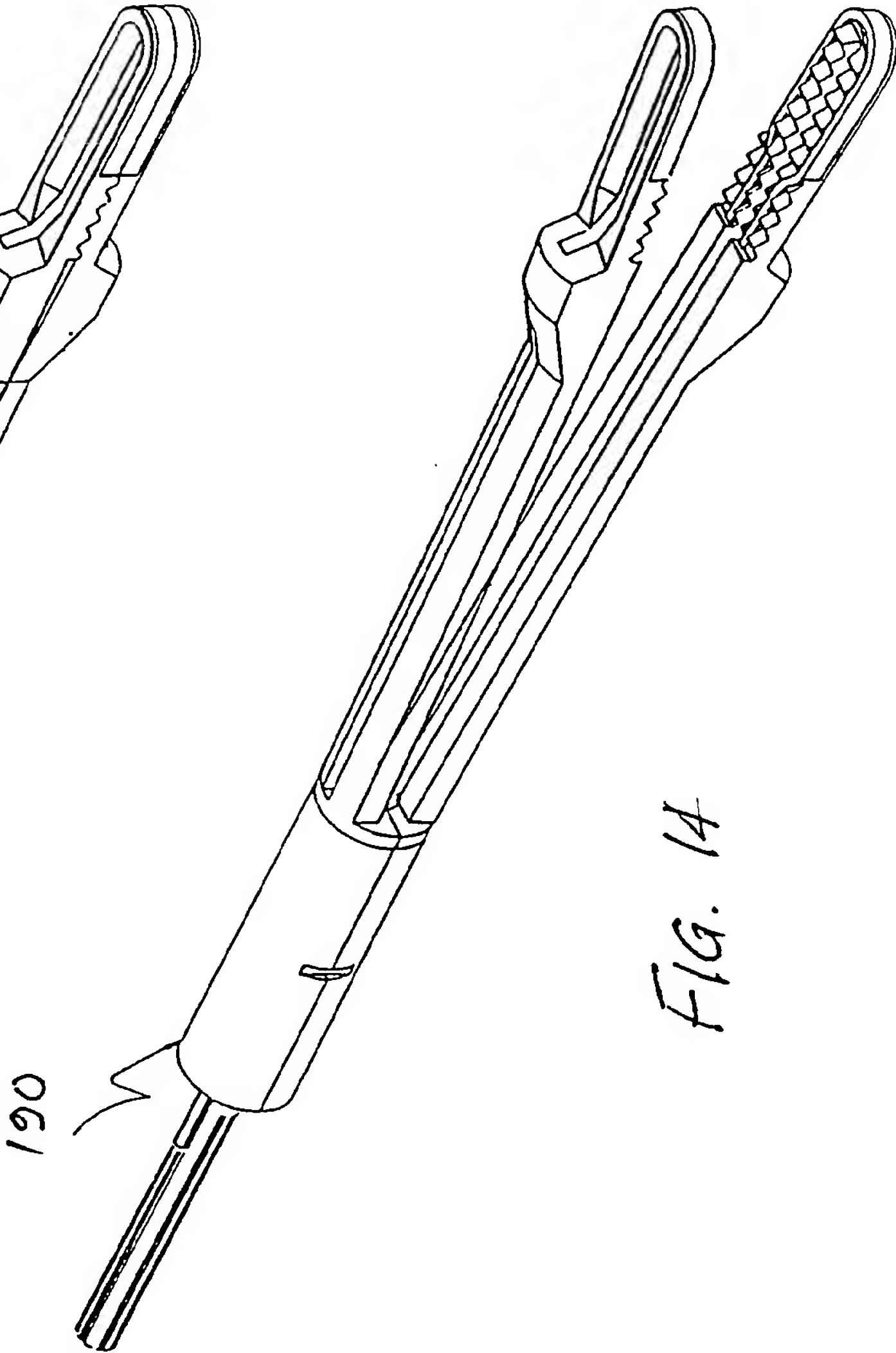
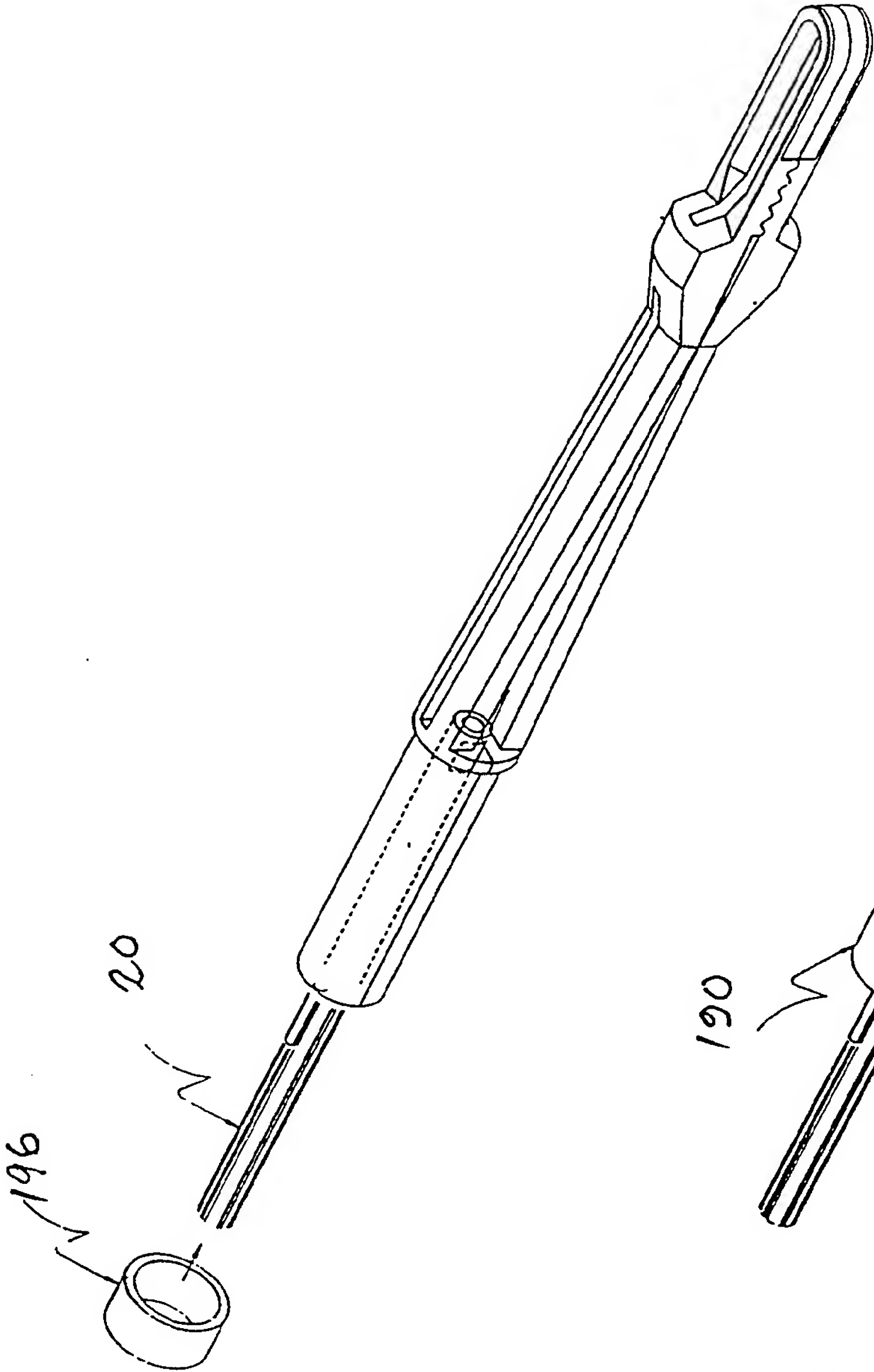
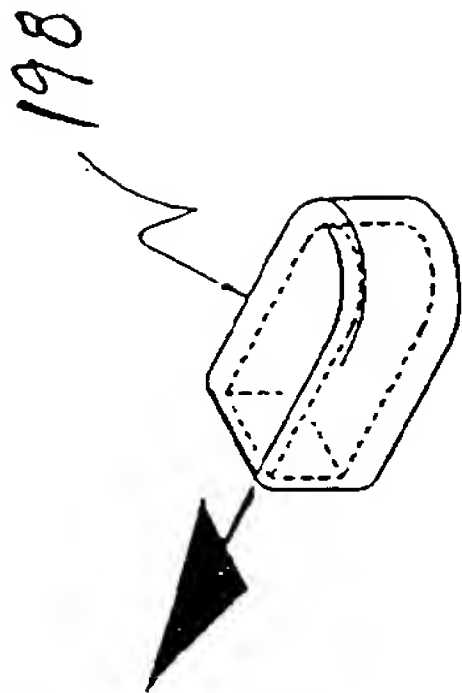
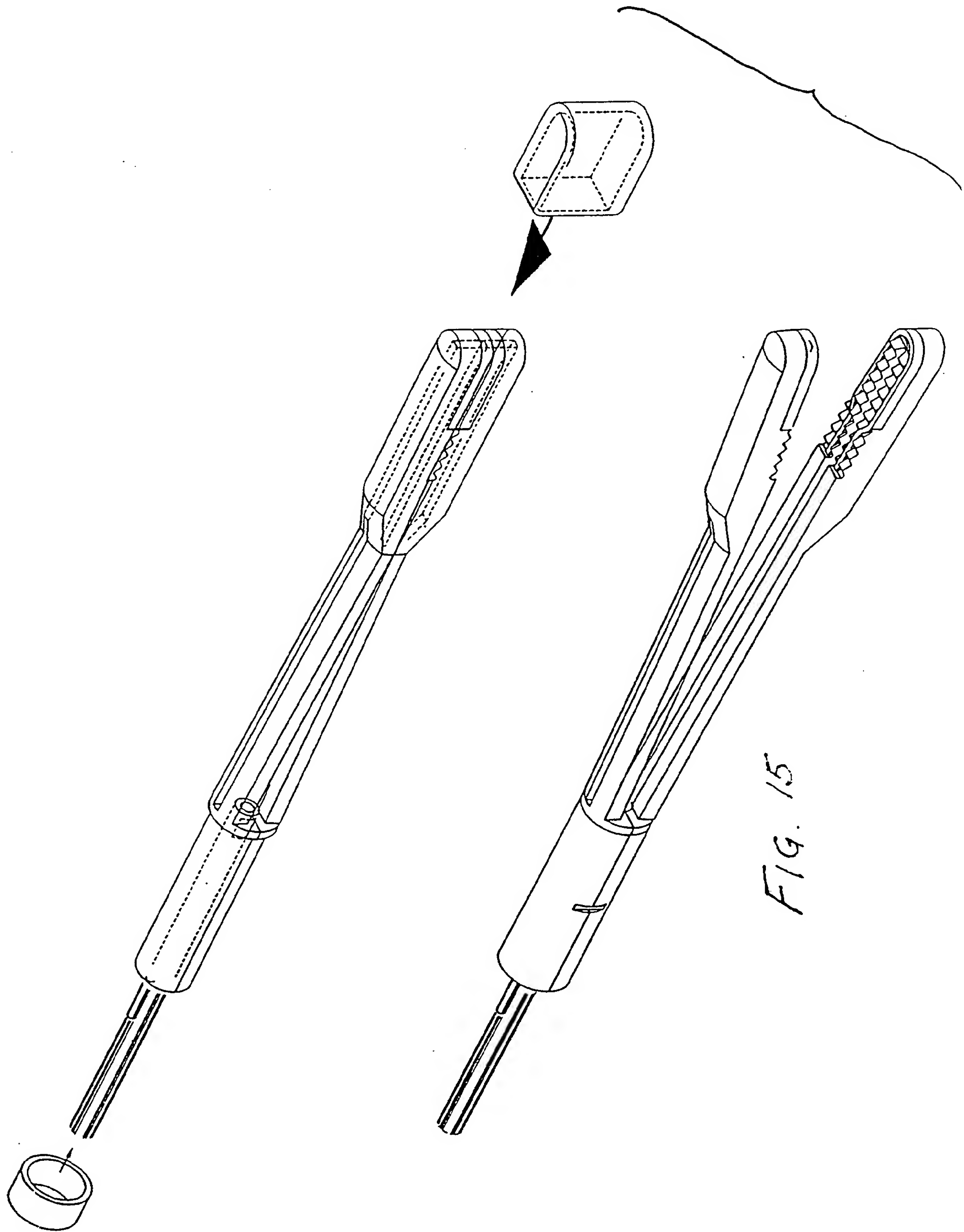
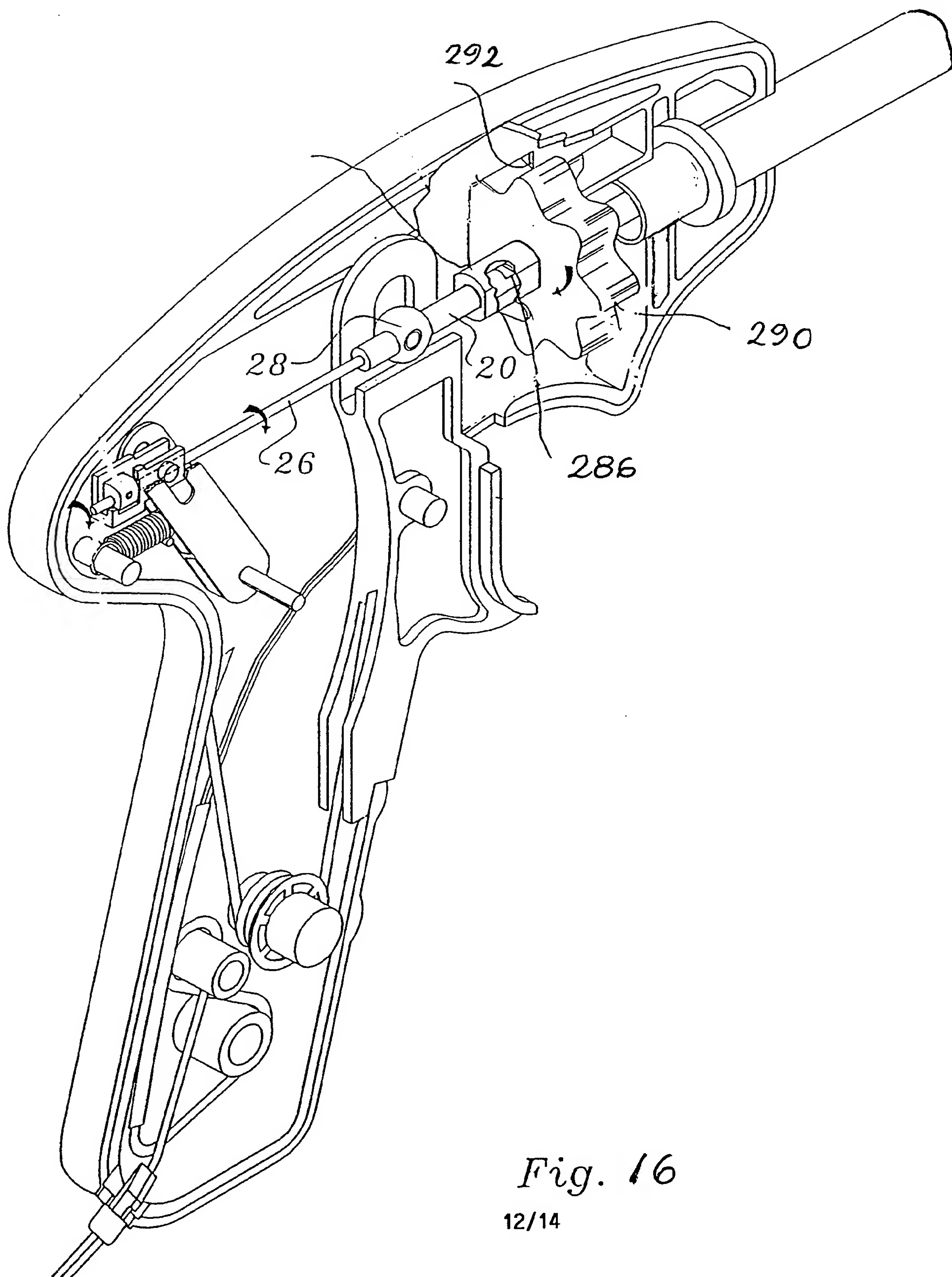
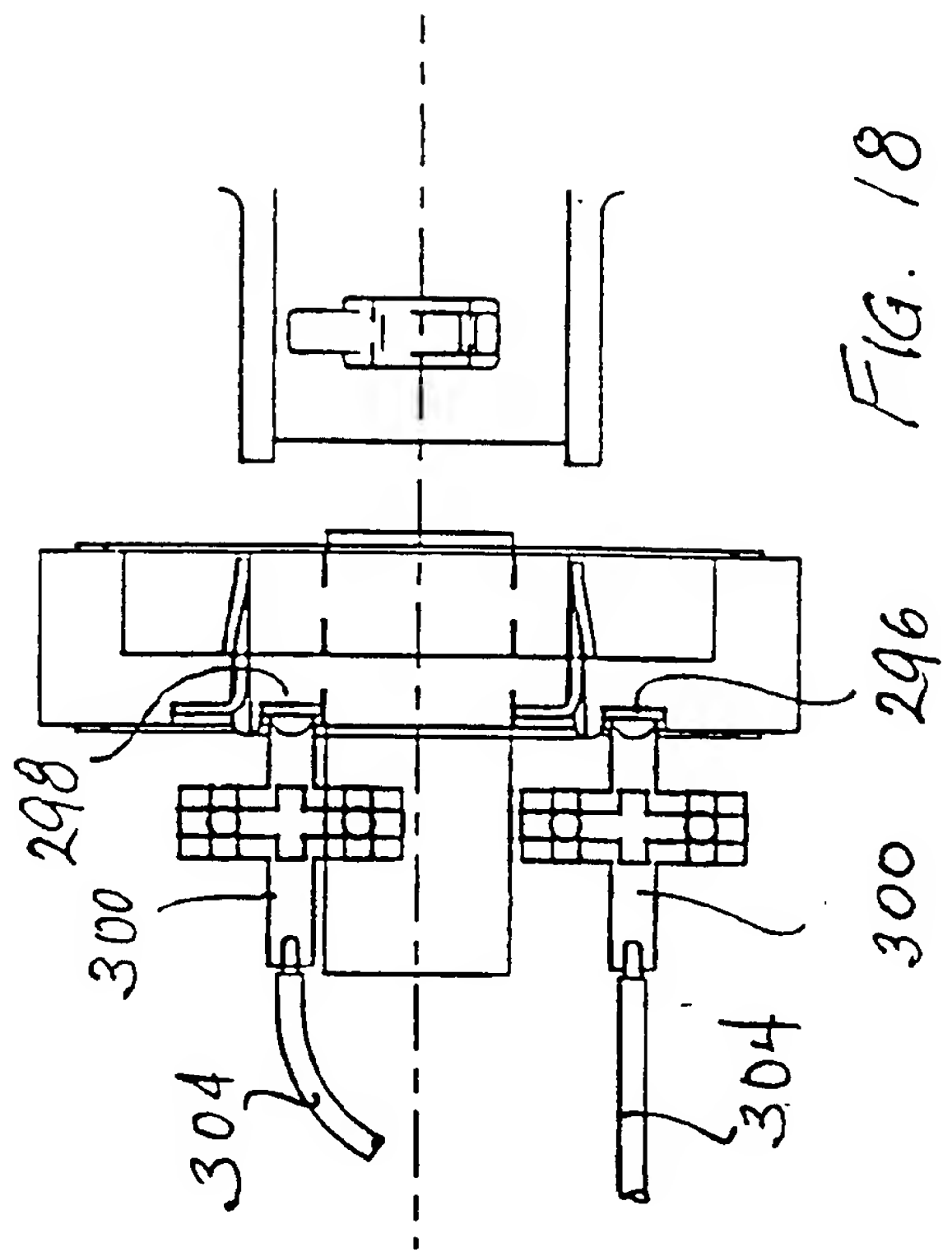
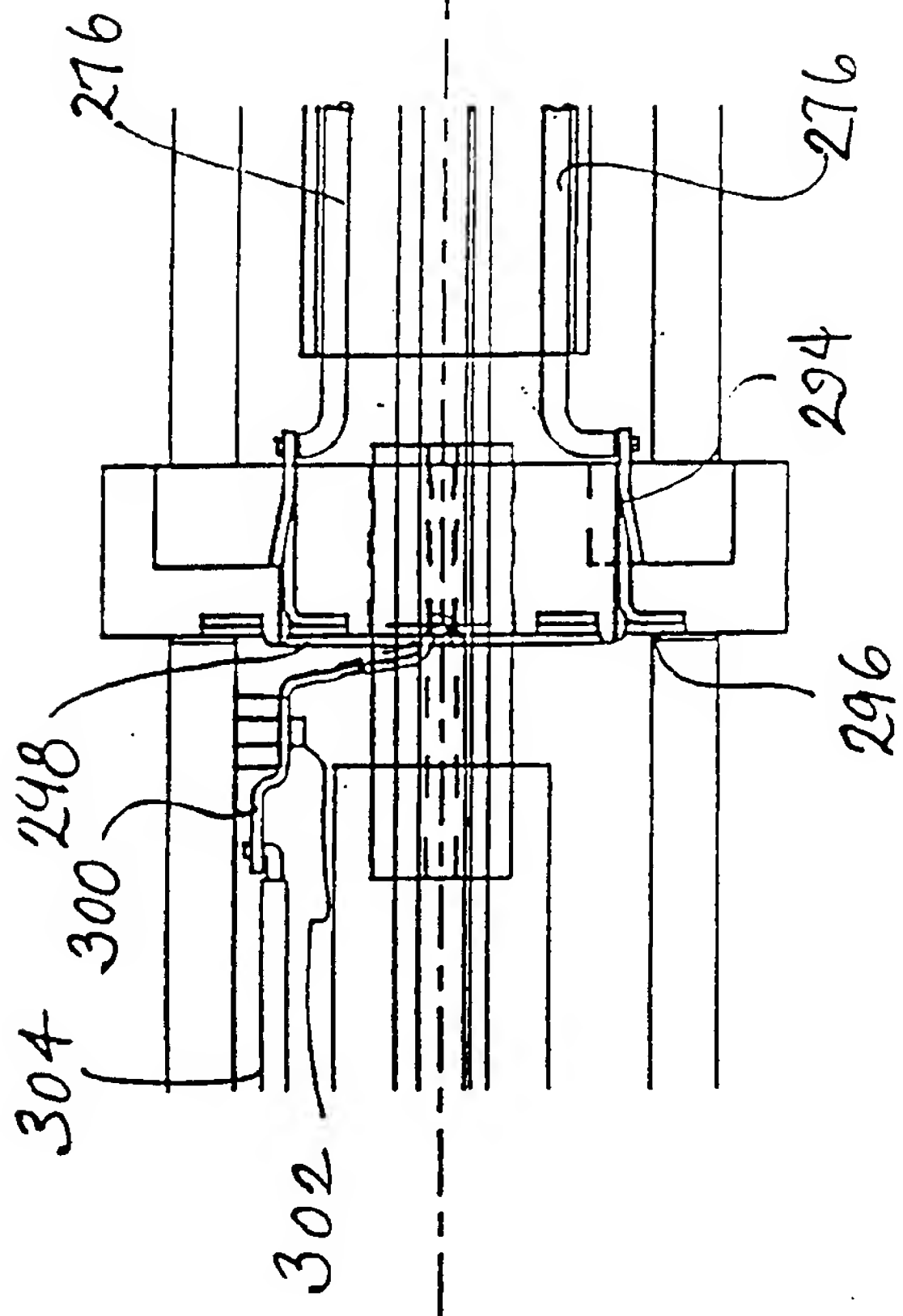
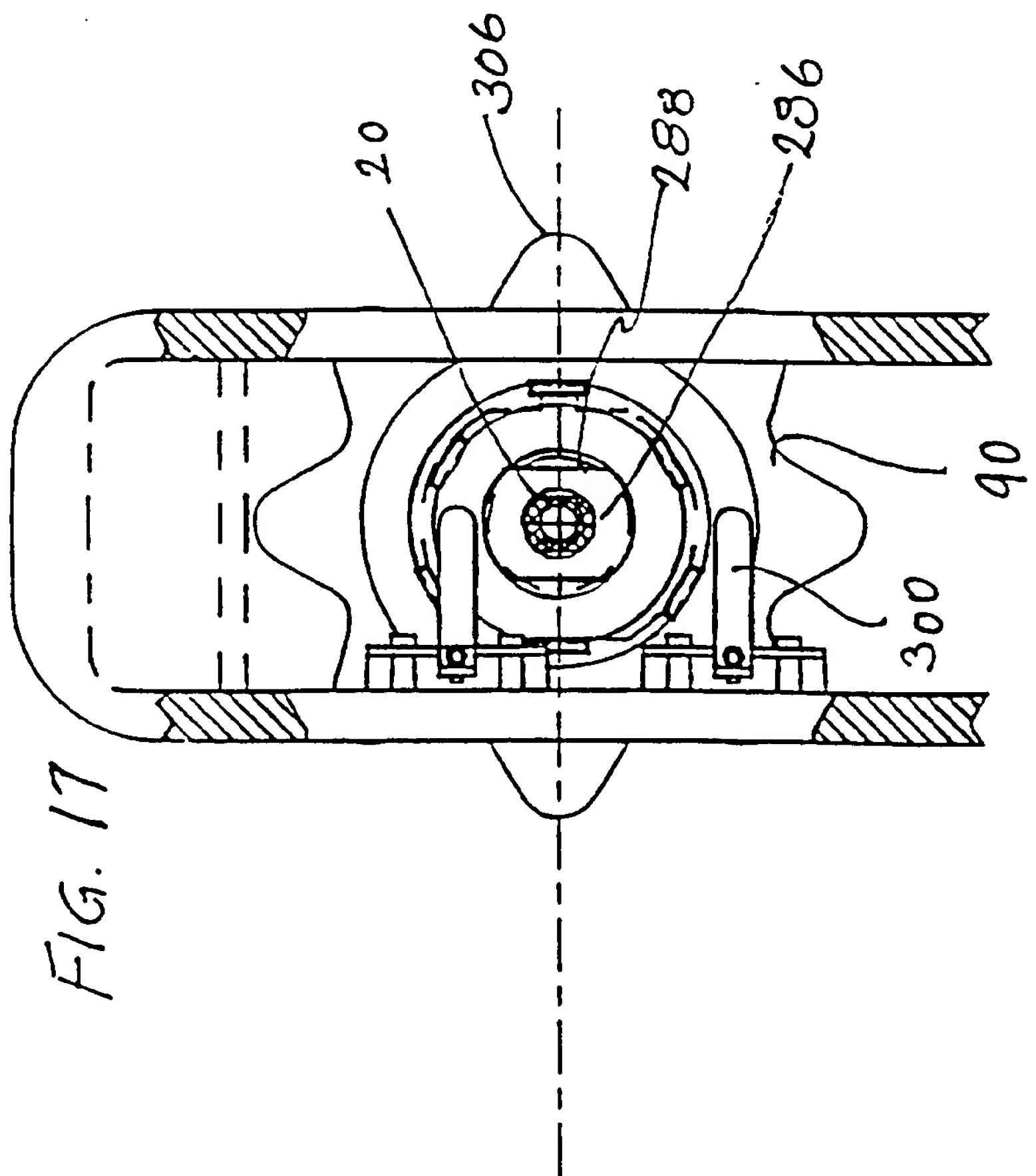


FIG. 14





*Fig. 16*



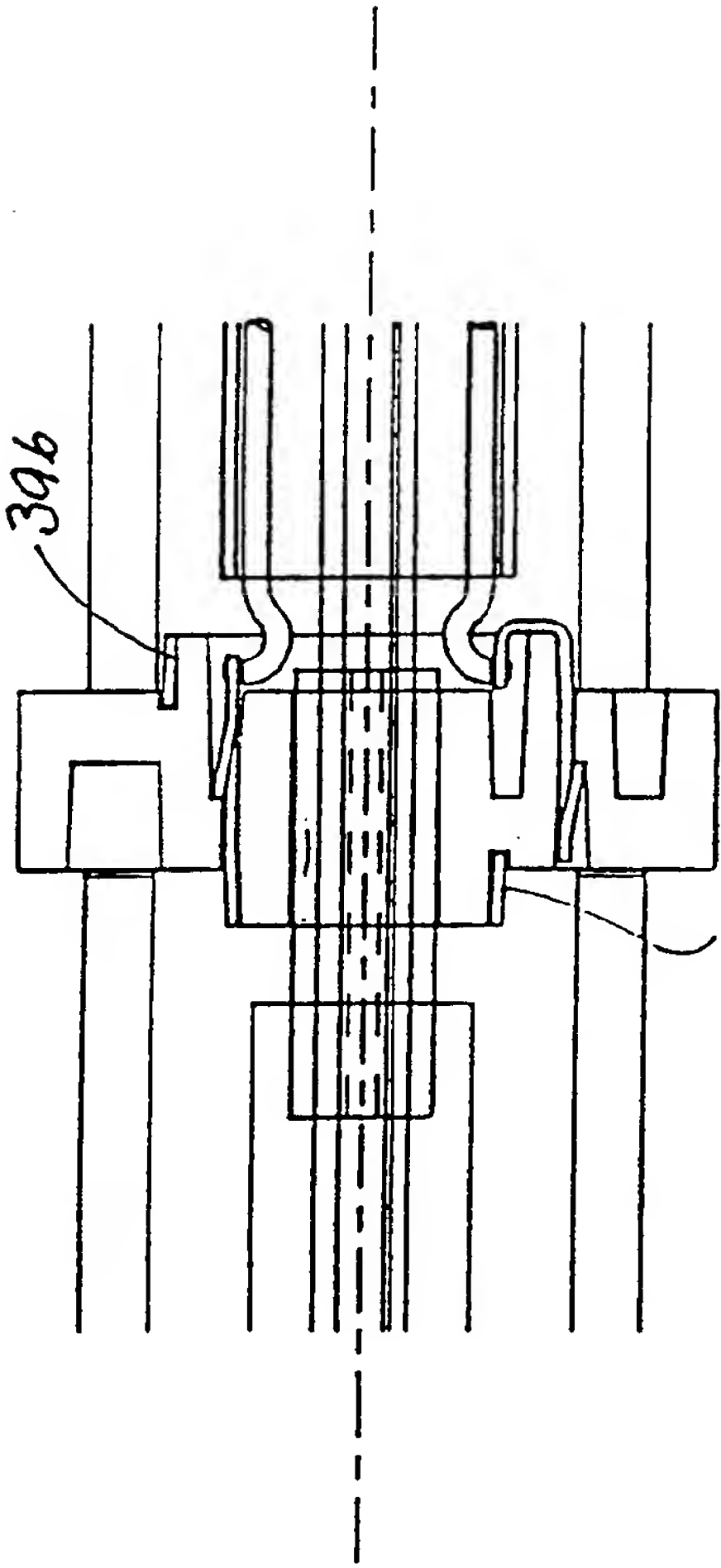


FIG. 22 98

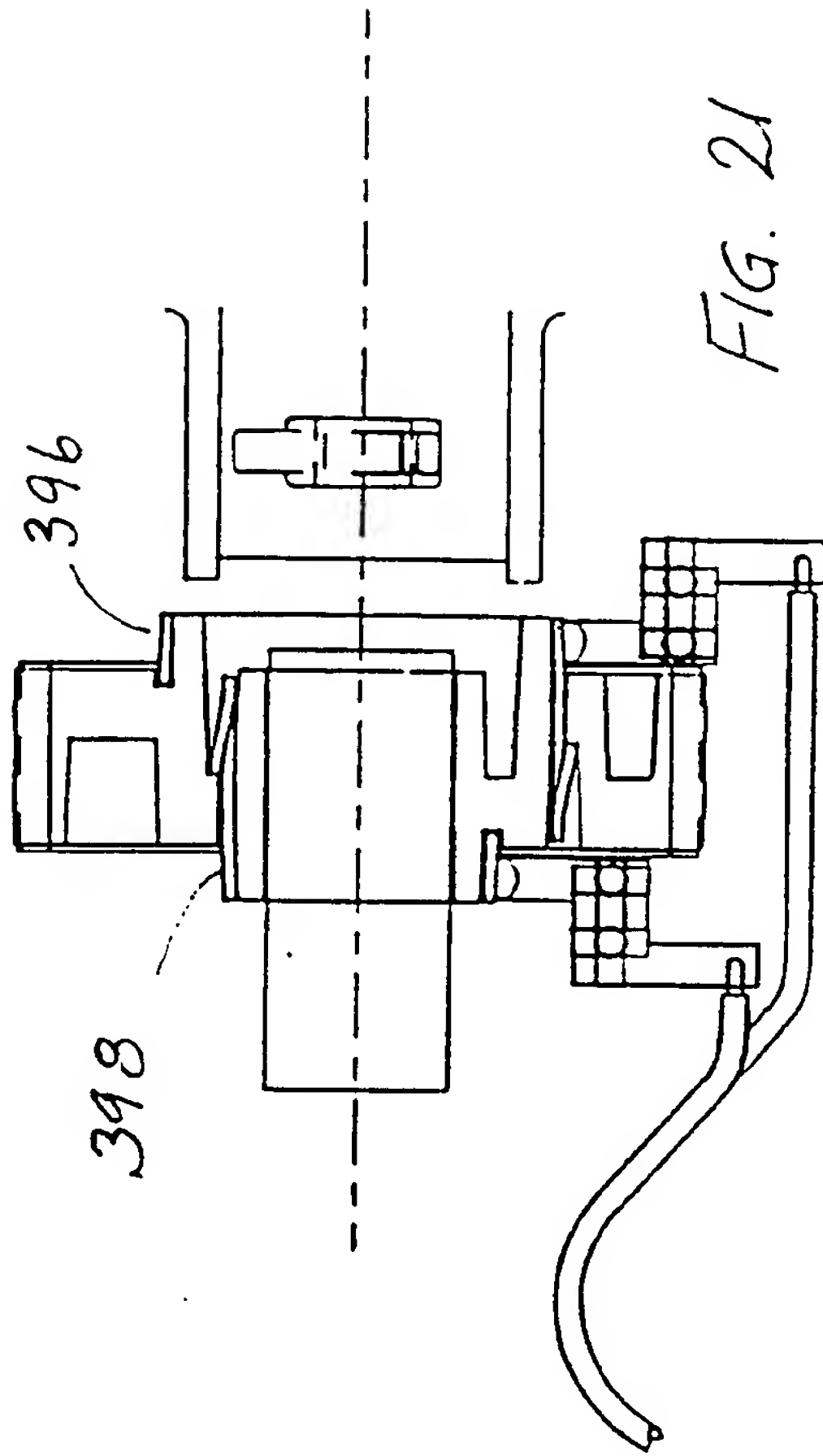


FIG. 21

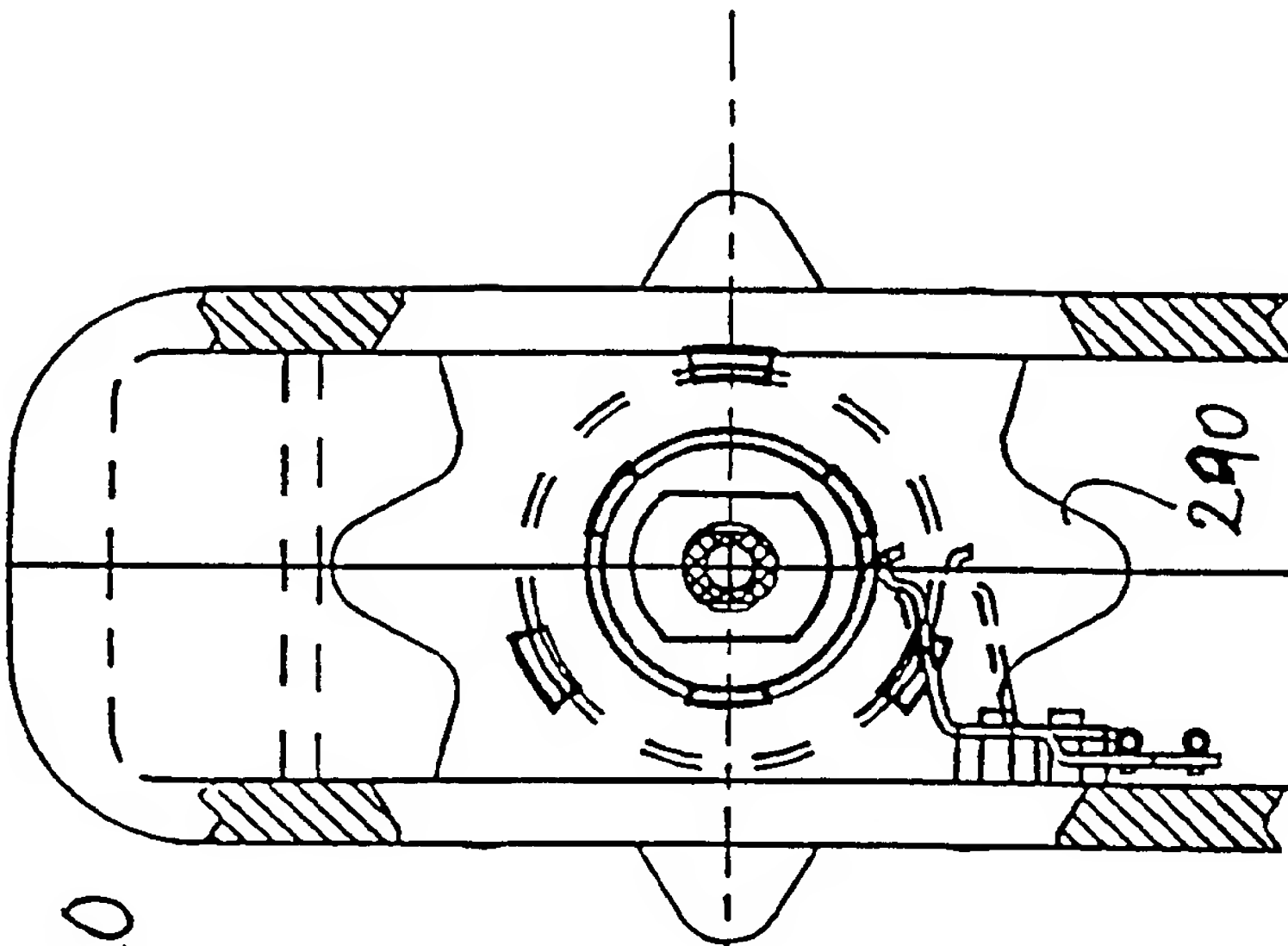


FIG. 20

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/12919

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36

US CL :606/41, 205

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642, 751; 606/40-42, 45-52, 205-208

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US, A, 5,445,638 (RYDELL ET AL.) 29 August 1995, see whole document.	1-16
Y, P	US, A, 5,527,313 (SCOTT ET AL.) 18 June 1996, see whole document.	1-16
Y	US, A, 5,190,541 (ABELE ET AL.) 02 March 1993, see whole document.	1-16
Y	US, A, 5,396,900 (SLATER ET AL.) 14 March 1995, see whole document, particularly columns 5 and 6.	12-16
A, P	US, A, 5,443,463 (STERN ET AL.) 22 August 1995, see whole document.	1-25

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 SEPTEMBER 1996

Date of mailing of the international search report

10 OCT 1996

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Telephone No. (703) 308-4305

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/12919

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US, A, 5,540,684 (HASSLER, JR.) 30 July 1996, see whole document.	1-25